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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,889	06/26/2003	Cathy Klech Gelotte	MCP 275 CON 1	7232
27777	7590	12/10/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			JAGOE, DONNA A	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/607,889

Applicant(s)

GELOTTE ET AL.

Examiner

Donna Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

Claims 18-36 are pending in this application.

Response to Amendment

Objection of the specification is no longer maintained in view of the amendment submitted on 6 August 2004.

Response to Arguments

Applicant's arguments filed 6 August 2004 have been fully considered but they are not persuasive. The rejection made in the paper mailed 9 March 2004 under 35 U.S.C. §103(a) over Sunshine et al. is maintained and hereby repeated for the reasons set forth in the previous office action and those set forth below.

Applicant asserts that the suspending vehicle of Sunshine et al. is not necessarily water and further asserts that merely disclosing a water insoluble compound in water does not make a suspension.

The disclosure of Sunshine et al. teaches suitable pharmaceutical diluents, excipients or carriers suitably selected with respect to the intended form of administration i.e. elixirs, syrups, etc. The word **etc.** in the disclosure means that the disclosure is not limited to those elements recited, and includes those that would be obvious to one of ordinary skill in the art, such as adding suspending agents to an elixir/syrup formulation for an agent that is insoluble in water. While Sunshine et al. does not specifically recite "water" in the liquid formulation, Example 2, column 7, lines 20-45 recites a liquid formulation of Naproxen comprising orange flavoring and 10% alcohol. Clearly, this is a low-

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alcoholic elixir formulation, which, according to Remington's Pharmaceutical Science, has alcohol, glycerin, sucrose and purified water as ingredients (see Remington's Pharmaceutical Science, page 1240, column 1). Also, the patent makes it clear that other pharmaceutically acceptable formulations will be apparent to those skilled in the art of pharmaceutical formulations. The skilled artisan would know to add a suspending agent to the syrup or elixir formulation when an agent is sparingly soluble in water.

Regarding the taste-masking agent, as recited above, Example 2 recites orange flavoring, which would be a taste-masking agent.

Regarding the recitation of a "preserved syrup formulation" in the prior office action, the examiner apologizes for pointing applicant's representative to a non-existent column and line. The syrup or elixir of the patent is recited in column 5, line 50 to column 6, line 61. Regarding claims 26-28 and 34-36, applicant asserts that, since the prior art does not disclose, *inter alia*, a suspension and a taste-masking agent, it is not seen where the claimed subject matter is an "old product". As previously discussed, the disclosure of Sunshine et al. teaches suitable pharmaceutical diluents, excipients or carriers suitably selected with respect to the intended form of administration i.e. elixirs, syrups, etc. The word **etc.** in the disclosure means that the disclosure is not limited to those elements recited, and includes those that would be obvious to one of ordinary skill in the art, such as adding suspending agents to an elixir/syrup formulation for an agent that is insoluble in water. Taste-masking agents are recited in Example 2 of column 7 (orange flavoring).

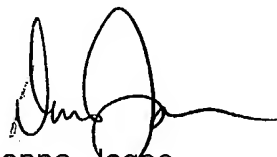
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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday and Thursday from 9:00 A.M. - 7:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Donna Jagoe
Patent Examiner
Art Unit 1614

12/8/2004



CHRISTOPHER C. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600